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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|-----------------|-------------|----------------------|--------------------------|------------------|
| 10/053,326      | 01/17/2002  | Satoru Kuhara        | JG-YY-4946D/500569.20085 | 4047             |

7590 01/02/2003

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EXAMINER

LU, FRANK WEI MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/053,326

Applicant(s)

KUHARA ET AL.

Examiner

Frank W Lu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/499,717.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Response to Amendment***

1. Applicant's response to the office action filed on October 7, 2002 has been entered as Paper No: 4. The claims pending in this application are claims 14-25. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is rejected as vague and indefinite in view of " an aqueous solution containing the oligonucleotide or the polynucleotide and a hydrophilic polymer" because it is unclear whether an aqueous solution containing the oligonucleotide also contains a hydrophilic polymer or not. Please clarify.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14, 17, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Rudolph (EP 0320842, published on June 21, 1989).

Regarding claims 14 and 22-25, Rudolph teaches to immobilize a biological agent such as RNA or DNA probes in the presence of a binding aid on a porous solid support and dry. The binding aid was a hydrophilic polymer including cellulose derivatives as recited in claim 23 and nonionic polymer such as saccharide as recited in claims 22 and 24. The process of drying the biological agent could be performed at higher temperature (considered as heating as recited in claim 14) (see columns 1-5). The most commonly used concentration for the binding aid was 1% as recited in claim 25.

Regarding claim 17, a nylon membrane used for immobilization of the biological agent was considered as a polymer sheet.

Therefore, Rudolph teaches all limitations recited in claims 14, 17, and 22-25.

6. Claims 14, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Carmichael (US Patent No. 5,728,518, published on March 17, 1998).

Note that this rejection was made in view of the ambiguity of claim 14 since it is unclear whether an aqueous solution containing the oligonucleotide also contains a hydrophilic polymer or not.

Carmichael teaches antiviral poly-and oligonucleotides. As shown in Example 1, the samples containing extracellular DNA denatured by NaOH were directly applied to nylon

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membranes presoaked in 20X SSC using a slot blot apparatus (BRL). To neutralize the bound DNA, slots were washed twice with 0.5 ml of 1M Tris, pH 7.2/2M NaCl and once with 0.5 ml of 20X SSC. The filters were removed, washed briefly in 2X SSC as recited in claim 16 and UV crosslinked (Stratalinker, Strategene) prior to hybridization with the full length HBV probe (see column 11, lines 30-48). Note that: (1) UV crosslinking the extracellular DNA on the nylon membranes was considered to expose the carrier to a radiation as recited in claim 14; and (2) the nylon membranes used for the slot blot was considered as a polymer sheet as recited in claim 17.

Therefore, Carmichael teaches all limitations recited in claims 14, 16, and 17.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph ( 1999) as applied to claims 14, 17, and 22-25 above, and further in view of Brown *et al.*, (US Patent No. 5,807,522, published on September 15, 1998).

The teachings of Rudolph have been summarized previously, *supra*.

Rudolph does not disclose to spot nucleic acids onto a glass sheet (slide) pretreated with poly-L-lysine as recited in claims 18 and 19.

Brown *et al.*, do teach to spot nucleic acids onto a glass sheet pretreated with poly-L-lysine (see columns 16-18).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids onto a glass sheet pretreated with poly-L-lysine in view of the prior art of Rudolph and Brown *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Rudolph because: (1) immobilization of nucleic acids onto a glass sheet pretreated with poly-L-lysine was known in the art at the time the invention was made and the use of a solid support with a layer of positive charges would enhance efficiency of the immobilization of nucleic acid (with negative charges) on the solid support; and (2) the simple replacement of one kind of solid support (i.e., nylon membrane) from another kind of solid support (i.e., glass slides pretreated with poly-L-lysine) in a method of fixing nucleic acid to a solid carrier would have

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been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

9. Claims 15, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph (1989) as applied to claims 14, 17, and 22-25 above, and further in view of Shi et al., (US Patent No. 5,919,626, published on July 6, 1999).

The teachings of Rudolph have been summarized previously, *supra*.

Rudolph does not disclose to spot nucleic acids with free hydroxyl groups at its one end onto a glass sheet (slide) pretreated with a silane coupling agent having an epoxy group as recited in claims 15, 18, and 20.

Shi *et al.*, do teach to spot nucleic acids with free hydroxyl groups at its one end onto a glass sheet pretreated with a silane coupling agent having an epoxy group (see columns 8, 14, 15, and 22).

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Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted nucleic acids with free hydroxyl groups at its one end onto a glass sheet pretreated with a silane coupling agent having an epoxy group in view of the prior art of Rudolph and Shi *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Rudolph because: (1) immobilization of nucleic acids onto a glass sheet pretreated with a silane coupling agent having an epoxy group was known in the art at the time the invention was made and immobilization of nucleic acids with free hydroxyl groups at its one end onto a glass sheet (slide) pretreated with a silane coupling agent having an epoxy group would enhance the stability of the immobilized nucleic acid on the glass sheet since the nucleic acids was covalently attached to a solid support in this process; and (2) the simple replacement of one kind of solid support (i.e., a nylon membrane) from another kind of solid support (i.e., glass slides pretreated with a silane coupling agent having an epoxy group) in a method of fixing nucleic acid to a solid carrier and the simple replacement of one kind of nucleic acid from another kind of nucleic acid (i.e., nucleic acids with free hydroxyl groups at its one end) in a method of fixing nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.



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Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

10. Claim 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudolph (1999) as applied to claims 14, 17, and 22-25 above, and further in view of Ghosh *et al.*, (Nucleic Acids Research, 15, 5353-5372, 1987).

The teachings of Rudolph have been summarized previously, *supra*.

Rudolph does not disclose to spot an aqueous solution containing a nucleic acid having an amino group onto a solid support as recited in claim 21.

Ghosh *et al.*, teach to attach a nucleic acid having an amino group onto a solid support (see page 5360).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have spotted an aqueous solution containing a nucleic acid having an amino group onto a solid support in view of the prior art of Rudolph and Ghosh *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Rudolph because the simple replacement of one kind of nucleic acid (i.e., a nucleic acid without an amino group) from another kind of nucleic acid (i.e., a nucleic acid having an amino group) in a method of fixing a nucleic acid to a solid carrier would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary

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skill in the art at the time the invention was made since the replacement of one kind of nucleic acid from another kind of nucleic acid would not change the experimental results.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

### ***Conclusion***

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu  
December 23, 2002

*ELW*  
*Ethan W. Lu*  
Primary Examiner